



དཔལ་ལྷན་འབྲུག་གཞུང་། གསོ་བ་ལྷན་ཁག་ འབྲུག་བཟང་འཆས་དང་སྤྲོད་རིགས་དབང་འཛིན།

ROYAL GOVERNMENT OF BHUTAN
MINISTRY OF HEALTH
BHUTAN FOOD AND DRUG AUTHORITY



BFDA/MPD/02/OFL/2025-2026/ 3976

16 March 2026

Regulatory Notification on Publication of List of Irrational Fixed Dose Combinations

In exercise of the powers conferred under the relevant provisions of the Medicines Act, Rules and Regulations of Bhutan, the Bhutan Food and Drug Authority (BFDA) hereby notifies all concerned stakeholders regarding the publication and regulatory enforcement of a List of Irrational Fixed Dose Combinations (FDCs).

The Bhutan Food and Drug Authority has published a list of FDC medicinal products that have been identified as irrational, based on scientific evidence, safety, efficacy, and public health considerations. The published list shall be deemed an official regulatory reference for rejection of FDC medicinal products submitted for registration.

This notification shall apply to, but not be limited to:

1. Market Authorization Holders (MAHs) applying for registration or re-registration
2. Importers applying for import authorization
3. Procurement agencies involved in procurement of medicinal products

Any application for registration or renewal of medicinal products that are included in the published list of irrational FDCs shall be rejected during the marketing authorization evaluation process. In addition, any application seeking import authorization for such products shall be rejected by the Authority.

All Market Authorization Holders, importers, and procurement agencies are hereby directed to strictly adhere to this notification. Failure to comply with this notification may result in regulatory actions in accordance with the applicable laws and regulations.

The list of irrational FDCs shall be reviewed and updated as and when required, based on emerging scientific evidence, safety concerns, or regulatory decisions of the reference NRA. Updated lists shall be published through official BFDA communication channels.

For further clarification, applicants may contact the Medical Product Division, BFDA, via mpd@bfda.gov.bt or call us at 1555.

This notification is issued for information, and strict compliance.

Director